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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/666,154

09/19/2003

Bryan Windus-Smith

DDI-5016

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7590

10/16/2007

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EXAMINER

REYNOLDS, STEVEN ALAN

ART UNIT

PAPER NUMBER

3728

MAIL DATE

DELIVERY MODE

10/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/666,154

Applicant(s)

WINDUS-SMITH ET AL.

Examiner

Steven Reynolds

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/12/07, 8/31/07, 8/31/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment filed on 9/4/2007, wherein claims 4 and 5 were canceled. Claims 1-3 and 6-18 are pending.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 2, 6-9, 11-13 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Magney (US 4,180,162). Magney discloses a medical device package comprising a main cap member (box 10 in combination with cover 14) with a cavity therein, the main cap member including: a proximal end; and a distal end; and a minor cap member (18); a connector (scalpel handle 31); wherein the cavity has a cavity opening at the proximal end of the main cap member; the cavity is capable of receiving, and to securely and removably retain, a medical device with electrical contacts partially therein such that the electrical contacts project from the cavity opening and minor cap member, and the minor cap member is capable of sealing the cavity opening once the medical device has been partially received in the cavity; the connector is configured to engage the medical device during removal of the medical device from the cavity and includes a strip engaging element (boss 33) capable of contacting electrical contacts; the main cap member includes at least one lateral channel (channel between 17 and 26) and wherein the medical device is securely and removably retained by a friction fit

between the medical device and the at least one lateral channel; the minor cap member is breachable; the minor cap member is capable of permanent attachment to the medical device; the main cap member further includes a distal end cavity capable of disabling the medical device; and the connector is capable of breaching the minor cap member.

Further regarding claims 13 and 15-18, Magney discloses the method for extracting a medical device including the steps of breaching the minor cap member with the connector such that at least a portion of the connector has entered the cavity of the medical device cavity; engaging the medical device with the connector; extracting the connector and engaged medical device from the cavity of the medical device package; subsequently inserting the connector and engaged medical device into a cavity of the medical device package to a second position whereby the medical device is disabled from subsequent use; the inserting step includes inserting the engaged medical device into the distal end cavity of the main cap member; disengaging the connector from the disabled medical device; and withdrawing the connector from the medical device package.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magney (US 4,180,162) in view of Vidal et al. (US 4,903,390). As described above, Magney discloses the claimed invention except for the directional marker on the main cap member. However, Vidal et al. teaches a medical device package comprising a main cap member including an arrow (61) for the purpose of indicating that the scalpel is to be inserted with the cutting edge of the blade extending upwardly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the main cap member of Magney with an arrow as taught by Vidal et al. to indicate to the user which direction to insert the medical device into the cavity.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magney (US 4,180,162) in view of Newman et al. (US 2002/0143352). As described above, Magney discloses the claimed invention except for the specifics of the connector. However, Newman et al. teaches a connector (scalpel handle) comprising a shield (40) slidably mounted to the scalpel to prevent inadvertent access to the blade, including arrows (28) on the scalpel for the purpose of visual indication to the user of the direction in which the shield should be moved. Therefore, it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to have modified the connector (scalpel handle) of Magney with the shield and arrows as taught by Newman et al. in order to shield the medical device (blade) when not in use.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magney (US 4,180,162) in view of Charlton (US 2003/0036200). As described above, Magney discloses the claimed invention except for the specifics of the medical device. However, Charlton teaches a medical device (test sensor 120) comprising a tissue penetration member and a test strip for the purpose of collecting and testing a sample of blood. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the medical device package of Magney to store the medical device as taught by Charlton in order to safely dispose the used medical device.

Response to Arguments

8. Applicant's arguments filed 9/4/2007 have been fully considered but they are not persuasive. Regarding the intended use of the claimed invention "configured to receive, and to securely and removably retain a medical device with electrical contacts partially therein such that the electrical contacts project from the cavity opening and minor cap member", it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. If the

prior art structure is capable of performing the intended use, then it meets the claim. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Reynolds whose telephone number is (571) 272-9959. The examiner can normally be reached on Monday-Friday 9:00am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571)272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SR

10/9/07



Mickey Yu
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